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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,045	07/28/2003	David A. Potter	05524-003001/ 0240	7388

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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,045	POTTER, DAVID A.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-60 are presented for examination.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-5, 14-26 and 57-60, drawn to a method for treating an HIV-negative patient who has cancer, comprising administering to the patient a therapeutically effective amount of a compound of formula I or formula I in combination with formula II, classified in class 514, subclasses 274 or 365.

II. Claims 6-7 and 14-26, drawn to a method for treating an HIV-negative patient who has cancer, comprising administering to the patient a therapeutically effective amount of a compound of formula III, classified in class 514, subclass 473.

III. Claims 8-9 and 14-26, drawn to a method for treating an HIV-negative patient who has cancer, comprising administering to the patient a therapeutically effective amount of a compound of formula IV, classified in class 514, subclass 252.13.

IV. Claims 10-11 and 14-26, drawn to a method for treating an HIV-negative patient who has cancer, comprising administering to the patient a therapeutically effective amount of a compound of formula V, classified in class 514, subclass 601.

V. Claims 31, 37-40, 48-49, 54 and 56, drawn to methods for predicting whether a patient will respond to treatment with a composition comprising a calpain

inhibitor, wherein the composition contains a compound of formula I or formula I in combination with formula II, classified in class 424, subclass 9.2; class 436, subclass 64; or class 514, subclasses 274 or 365, for example.

VI. Claims 31, 41-42, 49, 54 and 56, drawn to methods for predicting whether a patient will respond to treatment with a composition comprising a calpain inhibitor, wherein the composition contains a compound of formula III, classified in class 424, subclass 9.2; class 436, subclass 64; or class 514, subclass 473.

VII. Claims 31, 43-44, 49, 54 and 56, drawn to methods for predicting whether a patient will respond to treatment with a composition comprising a calpain inhibitor, wherein the composition contains a compound of formula IV, classified in class 424, subclass 9.2; class 436, subclass 64; or class 514, subclass 252.13.

VIII. Claims 31, 45-46, 49, 54 and 56, drawn to a method for predicting whether a patient will respond to treatment with a composition comprising a calpain inhibitor, wherein the composition contains a compound of formula V, classified in class 424, subclass 9.2; class 436, subclass 64; or class 514, subclass 601.

IX. Claims 32-35, drawn to a method for selecting a treatment regime for a patient who has cancer, classified in class 424, subclass 9.2.

Claims 1, 12-13 and 27-29 link Inventions I through IV and claims 30, 36, 47, 50-53 and 55 link Inventions V through VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 27-29 or claims 30, 36, 47, 50-53 and 55. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all

the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provision of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions as described in Groups I through IV are not considered related because each group is drawn to the use of a distinctly different compound for the treatment of an HIV-negative patient with cancer. For example, the invention of Group I requires the administration of a compound of formula I, which contains a 1,3-thiazole hetero-ring, to an HIV-negative patient with cancer, while the invention of Group II requires the administration of a compound of formula III, which contains a five-membered oxygen containing hetero-ring, to an HIV-negative patient with cancer. In light of the fact that the compounds are distinct and independent from one another, such that a comprehensive search for one of the compounds would not necessarily encompass any one or more of the other compounds, nor would the discovery of one of the compounds in the prior art used for the claimed therapeutic objective necessarily anticipate or

render obvious any one or more of the other claimed compounds, each of the inventions of groups I through IV are considered to have a distinctly different mode of operation or different function and are, thus, properly restricted.

Inventions V through VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions V through VIII are not considered related because each group is drawn to the use of a distinctly different compound for predicting whether a patient will respond to treatment with a composition comprising such compounds. For example, the invention of Group V requires the administration of a compound of formula I, which contains a 1,3-thiazole hetero-ring, to a patient, while the invention of Group VI requires the administration of a compound of formula III, which contains a five-membered oxygen containing hetero-ring, to a patient. In light of the fact that the compounds are distinct and independent from one another for the same reasons as applied above in the preceding paragraph, each of the inventions of groups V through VIII are considered to have a distinctly different mode of operation or different function and are, thus, properly restricted.

Invention IX and Inventions I through VIII are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method steps required to execute a method of Group IX drawn to selecting a treatment regime for a patient with cancer are distinctly different and independent from those required in any one or more of Groups I through VIII. For example, the

administration of a compound of formula I for the treatment of an HIV-negative patient with cancer is patentably distinct from providing cells from a cancer cell line, exposing said cells to at least two different compositions comprising a calpain inhibitor and determining which is more effective at killing the cells, reducing the motility of the cells or reducing the rate at which they grow or proliferate, as required in the method of Group IX. In light of the fact that the inventions are drawn to patentably distinct and independent subject matter, and further in light of the fact that a comprehensive search for a method of Group IX would not necessarily encompass a search for any one or more of the other methods of Groups I through VIII, restriction for examination purposes between Groups I through VIII and Group IX is proper.

Inventions I through IV and Inventions V through VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method steps required to execute a method of any one of Groups I through IV drawn to treating an HIV-negative patient with cancer are distinctly different and independent from those required in any one or more of Groups V through VIII. For example, the administration of a compound of formula I for the treatment of an HIV-negative patient with cancer is patentably distinct from predicting whether a patient will respond to treatment with a composition via treating cells with a composition and determining levels of expression of m-calpain or an EGF receptor, as required in, for example, the method of Group IV, since each has a distinctly different mode of operation, different function and a distinctly different outcome and each is practiced in a distinctly different population (i.e., cancerous cells vs. a host). In light of the fact that the inventions are drawn to patentably distinct and independent subject matter, and

further in light of the fact that a comprehensive search for a method of Groups I through IV would not necessarily encompass a search for any one or more of the other methods of Groups V through VIII, restriction for examination purposes between Groups I through IV and Groups V through VIII is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and further that the search required for any one of Groups I through IX would not result in a comprehensive search for any one or more of the other groups, restriction for examination purposes as indicated is proper.

Should Applicant elect the invention of any one of Groups I through IV, further election of an additional agent selected from the groups set forth below is also required:

(i) a pain relief agent (claims 14 and 15);

(ii) an antinausea agent (claim 14);

(iii) an anticancer agent other than ritonavir, lopinavir or amprenavir (claims 14 and 16-18);

(iv) an inhibitor of P-glycoprotein (claims 19-20);

(v) an inhibitor of an EGF receptor or erbB2 (claims 21-24);

(vi) a proteasome inhibitor (claims 25-26).

Should Applicant elect group (iii), drawn to anticancer agents, as the group of additional agent(s) to be used, further election of one of the following groups of anticancer agents is required from the groups set forth below:

(a) nitrogen mustards (including cyclophosphamide, melphalen or ifosfamide; claim 16);

(b) antimetabolites (including methotrexate, fluorouracil, cytarabine, fludarabine or 2-CDA; claim 16);

(c) antibiotics (including dactinomycin, doxorubicin, daunorubicin, mitoxantrone, bleomycin, mitomycin, doxycycline or epirubicin; claim 16);

(d) vinca alkaloids (including vincristine, vinblastine or vinorelbine; claim 16);

(e) biologic response modifiers (including IL-2 or interferon; claim 16);

(f) epipodophyllotoxins (including etoposide or teniposide; claim 16);

(g) antimicrotuble agents (including paclitaxel or docetaxel; claims 16-17);

(h) hormonal agents (including tamoxifen, flutamide, prednisolone, leuprolide, toremifene, anastrozole, fulvestrant, reloxifine or letrozole; claim 16);

(i) procarbazine (claim 16);

(j) platinum compounds (including cisplatin or carboplatin; claims 16 and 18);

(k) leucovorin (claim 16);

(l) nitrosoureas (including streptozocin; claim 16); or

(m) monoclonal antibodies (including rituximab or campath; claim 16).

Should Applicant elect the invention of any one of Groups V through VII, further election of an agent with which the composition is tested in conjunction, selected from the groups set forth below is also required:

(vii) a pain relief agent (claim 49);

(viii) an antinausea agent (claim 49);

(ix) an anticancer agent other than ritonavir, lopinavir or amprenavir (claim 49);

(x) an inhibitor of P-glycoprotein (claim 49);

(xi) an inhibitor of an EGF receptor (claim 49);

(xii) a proteasome inhibitor (claim 49).

Claims 14-24 and 49 are generic to a plurality of disclosed patentably distinct species comprising the species of additional agents as set forth above. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Catherine McCarty at the office of Fish and Richardson on Friday, September 23, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 23, 2005